IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

PAUL LISENBY	:	**CIVIL ACTION**
	:	
	:	
v.	:	**NO. 24-1803**
	:	
OLYMPUS CORPORATION OF THE AMERICAS, et al.	:	
	:	

MEMORANDUM

SCHMEHL, J. /s/ JLS **FEBRUARY 25, 2025**

Plaintiff brought this action, claiming the Defendants terminated him from his position as Global Head of Product Development in retaliation for trying to prevent one or more violations of the False Claims Act, 31 U.S.C. § 3730(h)(2) (Count One), and in violation of the Pennsylvania Whistleblower Law 43 P.S. § 1422 (Count Two), and the Florida Private Whistleblowers Act (Count Three). Presently before the Court is the Defendants' motion to dismiss all counts of the Amended Complaint pursuant to Fed. R. Civ. P. 12(b)(6) for failure to state a claim upon which relief can be granted. For the reasons that follow, the motion is granted. Count One will be dismissed with prejudice. The Court will decline to exercise pendent jurisdiction over the remaining two state claims and, therefore, Counts Two and Three will be dismissed without prejudice.

Under Rule 12(b)(6), the court must "accept all factual allegations as true [and] construe the complaint in the light most favorable to the plaintiff." *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008). Only if "the '[f]actual allegations ... raise a right to relief above the speculative level'" has the plaintiff stated a plausible claim. *Id.* at 234 (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 540, 555 (2007)). "A claim has facial

plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). However, "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." *Id.* (explaining that determining "whether a complaint states a plausible claim for relief ... [is] a context-specific task that requires the reviewing court to draw on its judicial experience and common sense").

According to the Amended Complaint, Plaintiff worked for Defendants[1] as the Global Head of Product Development from May 2022 to March 2024. Am. Compl. at ¶ 18. Plaintiff primarily worked from his home in Florida. *Id.* at ¶ 20. Plaintiff reported to Andre Roggan, the Chief Technology Officer of Olympus Medical Systems Corporation ("CTO Roggan"), who worked primarily from Tokyo, Japan; and to Julien Sauvagnargues ("Sauvagnargues"), the President of OCA, who worked primarily from Center Valley, Pennsylvania. *Id*. at ¶ 21.

Plaintiff's job responsibilities did not involve investigating fraud or compliance issues. *Id.* at ¶ 23. "Rather, two other groups within Olympus were responsible for compliance: the Regulatory Affairs Group and the Product Quality Assurance Group." *Id. at ¶ 24.*

[1] Defendants Olympus Corporation of the Americas ("OCA"), Olympus America, Inc. ("Olympus America") and Gyrus ACMI, Inc. ("Gyrus") are wholly-owned subsidiaries of Olympus Corporation, which has a principal place of business located in Tokyo, Japan. Am. Compl. at ¶¶ 6-9. Plaintiff was employed by Gyrus. *Id*. at 18-19. All three Defendants are part of a single enterprise, which also includes Olympus Corporation, Olympus Scientific Solutions, and Olympus Medical Systems Corporation. *Id*. at ¶ 10. All three Defendants receive federal and state financial assistance. *Id*. at ¶ 11. Olympus America is a federal contractor that receives over $85 million annually in federal awards. *Id. at ¶ 12.* All three Defendants sell medical device products to the federal government, including to the Department of Veterans Affairs. *Id*. at ¶ 13. The Department of Veterans Affairs was Olympus' largest customer in the United States. *Id*. at ¶ 14. All three Defendants sell their products to hospitals and other entities that receive Medicare and Medicaid reimbursements in most or all states, including but not limited to Pennsylvania and Florida. *Id*. at ¶ 15.

Based on his extensive experience in the medical device field, Plaintiff was very knowledgeable about the requirements for the approval of medical devices by the Food and Drug Administration ("FDA.") *Id*. at ¶ 25. According to Plaintiff, in 2023**, "**the FDA issued three warning letters to Olympus entities regarding their failure to comply with FDA standards." *Id*. at ¶ 26. Plaintiff witnessed additional occasions where Defendants failed to comply with FDA requirements, despite representing to the government and to the public that their devices had received approval from the FDA. *Id.* at ¶ 27. For example, "Defendants sold close to 100 products, including to the government and to the public, that they called "catch-up 510k" products, where Defendants internally acknowledged that they were not meeting FDA regulatory standards, and on which they planned to catch up and file new 510(k) filings." *Id.* at ¶ 28. "While "catch up" 510(k) filings are acceptable within the industry for small changes, a new 510(k) filing is required if the manufacturer changes form, fit, or function, or significant changes have been made to the original 510(k) filing for the device." *Id.* at ¶ 29. "The products on the "catch up" list had significant material changes to form, fit, and/or function that required new 510(k) filings in order to be FDA compliant. Specifically, new 510(k) filings and/or a voluntary recall of the products were required to address nonexistent device test data, incomplete design history files, missing biocompatibility testing, missing design verification and design validation tests, missing test method validations, incorrect statistical sample sizes, missing sample plans, incorrect risk management classifications, and nonexistent process validations." *Id.* at ¶ 30**.**

Despite knowing that these products did not comply with FDA regulatory standards and could "pose significant patient safety risks," Defendants continued to

market and sell these "catch up" products to the government and the public. *Id.* at ¶ 32. "Upon information and belief, most or all of the products on the catch-up 510(k) list were sold to the government, including to the Veterans Administration directly and to hospitals that submitted requests for Medicare and Medicaid reimbursement." *Id.* at ¶ 34. Plaintiff objected to these actions on "numerous occasions" and "outlined specific areas to both his direct management as well as outside of his chain of command where Olympus was violating FDA requirements." *Id*. at ¶ 33.

In 2023, Olympus Corporation planned to acquire Taewoong Medical Co., Ltd. ("Taewoong"), a Korean medical device company. *Id.* at ¶ 35. "During the due diligence period for this acquisition, Plaintiff learned that Taewoong devices were being made in workers' homes rather than in a sterile facility." *Id.* at ¶ 36. Such a practice would "unquestionably violate FDA standards." *Id*. at ¶ 37. According to Plaintiff, if Olympus acquired Taewoong, it would sell Taewoong products, including products made in employees' homes to the government, through sales to the VA and/or through Medicare/Medicaid reimbursement. *Id. at ¶ 38.* As a result, Plaintiff objected to the acquisition of Taewoong. *Id*. at ¶ 39. Despite Plaintiff's objection, his supervisor, CTO Roggan, went forward with the Taewoong acquisition, which closed in January 2024. *Id.* at ¶ 40. "However, In March of 2024, shortly after notifying Plaintiff of his termination, Olympus Corporation retracted its agreement with Taewoong due to "data integrity issues." *Id.* at ¶ 41.

Plaintiff also complained about "data integrity issues" with respect to other Olympus products on numerous occasions, but his complaints were ignored. *Id. at ¶ 42.* For example, in January and February 2024, Plaintiff traveled to Tokyo to attend

executive meetings. *Id.* at ¶ 43. At Chief Technology Officer ("CTO") Management Committee meetings during the week of January 29 through February 2, 2024, Plaintiff voiced his concern regarding his findings related to the failure of a "recent Olympus Hemostasis product launch called Quick-Clip Pro 2 (QCP2)." *Id*. at ¶ 45. According to Plaintiff, during surgical procedures the QCP2 device experienced a failure rate of 75%, "which also resulted in patient harm." *Id*. at ¶ 46. "During his subsequent investigation of the failure of QCP2, [Plaintiff] found several systemic deficiencies in Olympus' design approach and quality management system related to sample test sizes, insufficient design validations, inadequate supplier controls, missing test method validations, and process validations that did not comply with FDA requirements as set forth in 21 CFR Part 820." *Id.* at ¶ 47.

Plaintiff further discovered "that there were not sufficient quality management controls in-place, and fundamental testing had not been conducted to determine if the product was safe and efficacious prior to clinical use in patients." *Id.* at ¶ 48. As a result, Plaintiff "reasonably believed that if Olympus were to sell QCP2 in its current state, it would be misrepresenting data to the FDA to obtain approval, as it had done in the past." *Id*. at ¶ 49.

Plaintiff raised his concerns about a lack of product safety and FDA compliance issues during the CTO Management Committee meetings and thereafter, while providing examples. *Id.* at ¶ 50. On January 28, 2024, Plaintiff emailed CTO Roggan and Deputy CTO Tomohisa Sakurai ("CTO Sakurai") and provided links to a "proven design methodology called Design for Si**x** Sigma (DFSS) to address systemic quality issues and to improve product design." *Id*. He also "noted many documented systemic

issues, including late-stage design failures, poor sample size choices, missing product design requirements, poor test method validations, and supplier quality control failures." *Id*. at ¶ 57. Olympus sold products made in Japan and in Europe in the United States, including to the government. *Id.* at ¶ 61.

During the CTO Executive Meetings in Tokyo, Plaintiff specifically requested an additional formal meeting to discuss DFSS. *Id.* at ¶ 63. After numerous attempts by the Plaintiff, his request for a formal meeting was granted. *Id.* Although CTO Roggan did not attend the meeting, CTO Sakurai and other global R&D executive leaders did attend. *Id.* at ¶ 65. During the meeting, Plaintiff "detailed the findings of the QCP2 investigation as well as Olympus' systemic product development process issues and noncompliance to FDA standards." *Id*. at ¶ 64. While Plaintiff believed that the group acknowledged the "significant compliance and testing gaps in Olympus product development process" as well as the use of DFSS to address these issues, Plaintiff was informed that any changes would have to be approved by CTO Roggan. *Id.* CTO Roggan never met with or spoke to Plaintiff about his concerns. *Id*. at ¶ 69. [2]

Having not received a response from CTO Roggan to his January 28, 2024 email, Plaintiff followed up with CTO Roggan on February 1, 2024. *Id.* at ¶ 66. On February 7, 2024, CTO Roggan responded that "he had not yet reviewed the DFSS

[2]Plaintiff also alleges that he spoke with the then Global Head of the Therapeutic Solutions Division, Gabriela Kaynor, on January 21, 2024, Vice President/General Manager of the GI Endo-Therapy Business Unit, Mike Callaghan, later that same week, Global VP of Quality Design and Assurance, Eric Rainis, on February 12, 2024, and Senior VP of Regulatory Affairs, Todd Brill, on February 13, 2024. *Id*. ¶¶ 51, 54-55, 70-71, 74. Plaintiff alleges that during these meetings, he expressed concerns relating to Olympus' purported failures to comply with FDA testing and compliance standards in connection with its product development processes and offered recommendations to improve those processes (such as use of DFSS). *Id*. ¶¶ 52, 54-55, 70-72, 74. Plaintiff alleges during his conversation with Kaynor, he referenced the failure of the QCP2 and its prior generation, the Quick Clip Pro 1. *Id*. ¶ 52. Plaintiff alleges that despite a voluntary recall, Defendants continued to sell the QCP1 in the United States and other locations. *Id*. at ¶ 53.)

methodology, and it should be pre-screened by CoE, a lower-level R&D subcommittee." *Id*. at ¶ 68. "To the best of [Plaintiff's] knowledge, Mr. Roggan did not have the DFSS methodology pre-screened by CoE and refused to even meet with [Plaintiff] to discuss his significant FDA compliance and patient safety concerns after repeated attempts." *Id*. at ¶ 69. On February 14, 2024, CTO Roggan notified Plaintiff that "his position had been eliminated in a reduction in force and he would no longer have a job." *Id*. at ¶ 77. No other positions were eliminated at that time. *Id*. at ¶ 79. According to Plaintiff, "Defendants have a need for the work performed by a Global Head of Product Development, such that its claim of a position elimination is pretextual." *Id*. at ¶ 81.

In Count One, Plaintiff claims that Defendants discharged him because "he engaged in efforts to stop one or more violations of the False Claims Act (FCA)." *Id.* at ¶ 84. "Specifically, the submission of false data to the FDA to obtain FDA approval would result in ill-gotten gains from the federal government. *Id*. at ¶ 85. Plaintiff alleges that FDA approval is a material condition of payment by the Centers for Medicare and Medicaid Services. See, e.g., 42 C.F.R. § 405.201(a)(1)."[3] *Id*. Plaintiff asserts that "Defendants have also sold devices to the Veterans Administration while representing that those devices were FDA-approved, and where FDA approval was a material condition of purchase." *Id*. at ¶ 86. Finally, Plaintiff alleges that "[b]y opposing the systemic failures that resulted in repeated FDA violations as set forth above, [Plaintiff] engaged in protected activity under the FCA." *Id*. at ¶ 87.

In general, to establish a *prima facie* violation of the FCA, plaintiff must prove that: "'(1) the defendant presented or caused to be presented to an agent of the United

[3] That regulation provides: "CMS uses the FDA categorization of a device as a factor in making Medicare coverage decisions." 42 C.F.R. § 405.201(a)(1).

States a claim for payment; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent.'" *U.S. ex rel Wilkins v. United Health Group, Inc.,* 659 F.3d 295, 305, *overruled on other grounds as recognized by United States ex rel. Freedom Unlimited, Inc. v. City of Pittsburgh*, 728 F. App'x 101 (3d Cir. 2018) (quoting *United States ex rel. Schmidt v. Zimmer, Inc.,* 386 F.3d 235, 242 (3d Cir.2004)). The purpose of the FCA is to protect against fraud "'that might result in financial loss to the Government.'" *Hutchins v. Wilentz, Goldman & Spitzer*, 253 F.3d 176, 183 (3d Cir. 2001) (quoting *United States v. Neifert–White Co.,* 390 U.S. 228, 232 (1968)); *See also Sefen ex rel. United States v. Animas Corp*., 2014 WL 2710957, at *8 (E.D. Pa. June 13, 2014). ("Integral to the analysis is whether the defendant submitted a false claim for payment that would financially impact the government.")

Under the FCA, "[a] false or fraudulent claim may be either factually false or legally false." *United States ex rel. Greenfield v. Medco Health Solutions, Inc*., 880 F.3d 89, 94 (3d Cir. 2018). A claim is factually false if the claimant misrepresents what goods or services it provided to the Government. *Id.* A claim is legally false if the claimant "lies about its compliance with a statutory, regulatory, or contractual requirement." *Id.* (quotations and citations omitted). This case involves legally false claims.

The Supreme Court has recognized two categories of legally false claims under the FCA—the "express false certification theory" and the "implied false certification theory." *Universal Health Servs. v. U.S. ex rel. Escobar*, 579 U.S. 176, 181 (2016). Under the "express false certification" theory, an entity is liable under the FCA for falsely certifying that it is in compliance with regulations which are prerequisites to Government

payment in connection with the claim for payment of federal funds. *See United States ex rel. Quinn v. Omnicare Inc.,* 382 F.3d 432, 441 (3d Cir. 2004). The implied false certification theory requires showing that the "defendant submits a claim for payment that makes specific representations about the goods or services provided, but knowingly fails to disclose the defendant's noncompliance with a statutory, regulatory, or contractual requirement." *United Health Services*, 579 U.S. at 181. To proceed on the grounds of an implied false certification, the plaintiff must plead sufficient facts to plausibly infer that the "defendant knowingly violated a requirement that the defendant knows is material to the government's payment decision." *Id*. This case involves the implied false certification theory.

The FCA also prohibits an employer from retaliating against employees who participate in investigating and prosecuting FCA violations. *Hutchins*, 253 F.3d at 185-86 (3d Cir. 2001) (citations omitted). Section 3730(h)(1) of the FCA provides:

> Any employee, contractor, or agent shall be entitled to all relief necessary to make that employee, contractor, or agent whole, if that employee, contractor, or agent is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment because of lawful acts done by the employee, contractor, agent or associated others in furtherance of an action under this section or other efforts to stop 1 or more violations of this subchapter.

31 U.S.C. § 3730(h)(1).

While substantive claims under the FCA are subject to the heightened pleading standard of Rule 9(b) of the Federal Rules of Civil Procedure, *Foglia v. Renal Ventures Mgmt*., 754 F. 3d 153, 155 (3d Cir. 2014), FCA retaliation claims are not subject to this standard. *United States ex rel. Grant v. United Airlines*, 912 F.3d 190, 200 (4th Cir.

2018). "Instead, a plaintiff need only satisfy Rule 8(a)'s notice-pleading standard." *Id.* "Accordingly, to sufficiently plead a § 3730(h) retaliation claim and thus survive a motion to dismiss, a plaintiff must allege facts sufficient to support a 'reasonable inference'" that 1) he was engaged in protected conduct and 2) that he was discriminated against because of the protected conduct. *United States ex rel. Ascolese v. Shoemaker Constr. Co.*, 55 F.4th 188, 194 (3d Cir. 2022).

Under the text of section 3730(h)(1), protected conduct encompasses either: 1) a lawful act done to further an FCA action; or 2) "other efforts to stop 1 or more violations of [the FCA]." 31 U.S.C. § 3730(h)(1). Our Court of Appeals has referred to these two provisions as the "FCA litigation prong" and the "'other efforts' prong." *Ascolese*, 55 F.4th at 194. The "other efforts" prong was enacted by Congress through 2009 and 2010 amendments to expand the FCA's anti-retaliation protections. *Id*. at 191,194. It includes taking action to prevent or halt violations or reasonably perceived violations of the FCA before they happen. *Id*.

Plaintiff does not allege in his Amended Complaint that he has filed or has contemplated filing an FCA action. Therefore, the Court must consider whether Plaintiff engaged in protected conduct under the "other efforts" prong.

As noted by this Court in *Hall v. Abington Memorial Hosp*., 2023 WL 6216526, at *3 (E.D. Pa. Sept. 25, 2023), our Court of Appeals has not yet adopted a test for determining what constitutes "other efforts to stop 1 or more violations of [the FCA]." This Court in *Hall*, did note, however, that "[c]ircuits that have reached the issue have clarified that plaintiffs raising an "other acts" retaliation claim must demonstrate that some nexus exists between their actions and the prevention of an actual or potential

violation of the FCA." *Id.* at *4; s*ee, e.g., United States ex rel. Reed v. KeyPoint Gov't Solutions*, 923 F.3d 729, 767 (10th Cir. 2019) ("a relator's actions still must convey a connection to the [FCA]"); *Hickman v. Spirit of Athens, Alabama, Inc.*, 985 F.3d 1284, 1288-89 (11th Cir. 2021) (plaintiffs "are, at a minimum, required to show that the activity they were fired over had *something* to do with the False Claims Act–or at least that a reasonable person might have thought so"). In other words, Plaintiff must demonstrate a nexus between his actions and that his employer knowingly submitted or planned to submit a false or fraudulent claim to the government for payment.

In *Hall*, this Court found the Eleventh Circuit's reasoning in *Hickman* to be particularly persuasive:

> An organization might commit, and its employees might believe it has committed, any number of legal or ethical violations–but the [FCA's] retaliation provision only protects employees where the suspected misdeeds are a violation of *the False Claims Act*, not just of general principles of ethics and fair dealing. It is not enough for an employee to suspect fraud; it is not even enough to suspect misuse of federal funds. In order to file under the [FCA], whether in a qui tam or a retaliation action, an employee must suspect that her employer has made a false claim to the federal government.

Hickman, 985 F.3d at 1289 (emphasis in original). *See also Smith v. Ideal Concepts, Inc.,* 2023 WL 8188446 at * 4 (E.D. Pa. Nov. 27, 2023). **(**"[T]he Amended Complaint fails to explain how the purported CMS violation renders any claim made to the federal government fraudulent or a potential FCA violation. Without a nexus to a viable FCA violation, Smith's conduct is not protected by the FCA's retaliation provision.")

This Court in *Hall* further recognized that an "objective reasonableness" test adopted by some circuits "can be applied as a workable, practical aid." *See Hall*, 2023 WL 6216526, at *4-5. Under that test,

> A belief is objectively reasonable when the plaintiff alleges facts sufficient to show that he believed his employer was violating the FCA, that this belief was reasonable, that he took action based on that belief, and that his actions were designed to stop one or more violations of the FCA. However, [] the plaintiff's actions . . . must still have a nexus to an FCA violation.

Hall at *4 (quoting *United States ex rel. Grant,* 912 F.3d at 201-02) (emphasis added).

In the case *sub judice*, Plaintiff alleges that his job responsibilities did not involve investigating fraud or compliance issues. *Id.* at ¶ 23. He further alleges that he reported to CTO Roggan and to Sauvagnargues. He therefore contends that when he raised Defendants' alleged systemic compliance issues not only with Roggan but also with executives Kaynor, Callaghan, Rainis and Brill, he was acting outside the scope of his normal job duties and was notifying a party outside the usual chain of command. Therefore, he claims he was engaging in protected activity under the FCA. Accepting these allegations as true, the Court finds that it does appear that Plaintiff was acting outside the scope of his normal job duties when he raised issues of Defendants' alleged failure to follow FDA testing and compliance standards. Crucially missing, however, are any allegations from which the Court can infer that Plaintiff was acting to prevent Defendants from submitting false and fraudulent bills to the FDA for payment.

With regard to the close to 100 "catch-up 510(k)" products that Plaintiff alleges in conclusory fashion were sold by the Defendants to the government and public without new 510(k) filings and, therefore, not in compliance with FDA regulatory standards, Plaintiff does not specifically identify a single one of the close to 100 or more "catch-up

510(k)" products.[4] Nor does he specify a single change to a particular device that would have warranted a new 510(k) filing. Clearly, even without the benefit of discovery, Plaintiff should be able to identify in an Amended Complaint at least some, if not all, of the products that he contends were sold to the government without new 510(k) filings. Plaintiff does not allege that he ever told any superior that the lack of new 510(k) filings with respect to any **particular** product put Defendants at risk under the FCA. As a result, Plaintiff's allegations do not provide the basis for the Court to find that Plaintiff held an objectively reasonable belief to suspect that the Defendants were knowingly making false claims to the government with respect to any **particular** product in violation of the FCA. In addition, given that the 510(k) filings constitute a legally false claim, it was incumbent upon Plaintiff to have specifically alleged that compliance with any FDA regulations which the Defendants allegedly violated concerning a particular "catch-up 510(k)" product was material to a payment decision by the government.[5] *Hall* at *7-8. Plaintiff has failed to do so.

Plaintiff also fails to plead facts to demonstrate that Defendants knowingly made or planned to make false or fraudulent claims for payment to the government in connection with the Taewoong Acquisition. In fact, Plaintiff does not allege Defendants

[4] Plaintiff's allegation that "[u]pon information and belief" most or all of the "510(k) catch-up" products were sold to the government, including the VA and to hospitals that submitted requests for Medicare and Medicaid reimbursement, is not permissible given that the Amended Complaint lacks specific facts upon which the information and belief is reasonably based. See *State Farm Mut. Auto. Ins. Co. v. Ficchi,* 2012 WL 1578247, at *5 (E.D.Pa. May 4, 2012). ("S]uch allegations are permissible "only if the pleading sets forth specific facts upon which the belief is reasonably based.").

[5] Although Plaintiff alleges in conclusory fashion that **"**FDA approval is a material condition of payment by the Centers for Medicare and Medicaid Services. See, e.g., 42 C.F.R. § 405.201(a)(1)," Am. Compl. at ¶ 85, and that "Defendants have also sold devices to the Veterans Administration while representing that those devices were FDA-approved, and where FDA approval was a material condition of purchase." *Id*. at ¶ 86, Plaintiff again fails to particularize what the products were that were allegedly sold to the CMS and the VA.

sold any Taewoong products to any entity. Instead, Plaintiff alleges that he had concerns, before the deal closed, that Taewoong products were being made in workers' homes rather than in a sterile facility and that, in his opinion, such a practice would "unquestionably" violate certain FDA standards, "such as those set forth in the Current Good Case Manufacturing Practices (CGMP) of the FDA's Quality Management System Regulation (QMSR) Final Rule." Plaintiff does not allege that Defendants, who were not affiliated with Taewoong at the time, sold or tried to sell Taewoong products to the government before the closing of the transaction or during the brief two-month period between the time the transaction closed (January 2024) and the time Olympus Corporation retracted the agreement (March 2024). Plaintiff merely assumes that Defendants would sell such Taewoong products to the government. *See United States ex rel. v. Beebe Healthcare*, 2024 WL 219395 at *13 (E.D. Pa. 2024.) ("Nor could [Plaintiff] have reasonably believed there was a violation because he had no basis for claiming fraudulent bills were submitted. He only assumed there must have been one.") In short, Plaintiff cannot demonstrate that Defendants knowingly tried to defraud the government in connection with devices they were not even alleged to be selling and may only hypothetically sell in the future.

Finally, Plaintiff's alleged actions in informing his superiors and other executives of Defendants about a lack of product safety and FDA compliance issues with respect to the QCP2 device also do not rise to the level of protected activity under the FCA. Plaintiff does not allege that the QCP2 was ever actually marketed or sold, let alone that Defendants submitted or planned to submit a single claim for payment to the government for the QCP2. Again, he merely assumes that they will be submitted, based

on the submission of the QCP1. Nor does Plaintiff's alleged proposal to his superiors of using the DFSS methodology to stop Defendant's alleged systemic violations of the FDA constitute protected activity as there is no allegation that the Plaintiff was doing so as a means of warning the Defendants that the government has been or will be defrauded by the Defendants' alleged lack of product safety and FDA compliance issues.

In short, this case is not so much about Defendants defrauding the government as it is about Plaintiff internally warning Defendants of alleged FDA regulatory violations and potential patient safety issues. However, by failing to demonstrate a nexus between the latter activity and a specific FCA violation, Plaintiff has failed to demonstrate that he did in fact engage in protected activity. *See Hutchins*, 253 F.3d at 187-88 ("Mere dissatisfaction with one's treatment on the job is not, of course, enough [to show protected activity]. Nor is an employee's investigation of nothing more than his employer's non-compliance with federal or state regulations.") After all, the FCA is not merely an "all-purpose antifraud statute or a vehicle for punishing garden-variety breaches of contract or regulatory violations." *Universal Health Servs.* 579 U.S. at 194. Since Plaintiff has failed to properly allege that he engaged in protected activity under the FCA, Plaintiff's retaliation claim under the FCA must be dismissed with prejudice.

Having dismissed the lone federal claim for failure to state a claim, the court declines to exercise supplemental jurisdiction over the remaining State law claims under the Pennsylvania and Florida Whistleblower Acts. 28 U.S.C. § 1367(c)(3). The "district court may decline to exercise supplemental jurisdiction over a claim if 'the district court has dismissed all claims over which it has original jurisdiction.'" *Elkadrawy v. Vanguard*

Grp., 584 F.3d 169, 174 (3d Cir.2009) (quoting 28 U.S.C. § 1367(c)(3)). "If it appears that the federal claim is subject to dismissal under Fed. R. Civ. P. 12(b)(6), then the court should ordinarily refrain from exercising jurisdiction in the absence of extraordinary circumstances." *Cito v. Bridgewater Twp. Police Dep't.,* 892 F.2d 23, 25–26 (3d Cir.1989). There are no extraordinary circumstances at bar that require the court to entertain the State law claims. Both of those claims are dismissed without prejudice with Plaintiff's right to file them in the appropriate state court.